

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

IMPACT APPLICATIONS, INC. :
9665 Granite Ridge Drive :
Suite 550 :
San Diego, California 92123 :

Plaintiff,

v.

Civil Action No.:

CONCUSSION MANAGEMENT, LLC, :
F/K/A XLNTBRAIN, LLC, D/B/A :
XLNTBRAIN AND :
XLNTBRAIN SPORT :
137 National Plaza :
Suite 300 :
National Harbor, Maryland 20745 :

and

HARRY KERASIDIS, M.D., :
individually and as trustee of the assets of :
CONCUSSION MANAGEMENT, LLC :
137 National Plaza :
Suite 300 :
National Harbor, Maryland 20745 :

and

STEVEN E. LEWIS, individually and as :
trustee of the assets of CONCUSSION :
MANAGEMENT, LLC :
137 National Plaza :
Suite 300 :
National Harbor, Maryland 20745 :

and

JURY TRIAL DEMANDED

JOHN DOES 1-10, individually and :
as trustees of the assets of :
CONCUSSION MANAGEMENT, LLC :
137 National Plaza :
Suite 300 :
National Harbor, Maryland 20745 :

Defendants. :

**COMPLAINT FOR
LANHAM ACT FALSE ADVERTISING AND UNFAIR COMPETITION**

Plaintiff, ImPACT Applications, Inc. ("ImPACT Applications"), by and through its undersigned counsel, brings this Complaint for Lanham Act False Advertising and Unfair Competition against Defendants Concussion Management, LLC f/k/a XLNTbrain, LLC ("XLNTbrain"); Harry Kerasidis, M.D., individually and as trustee of the assets of XLNTbrain; Steven E. Lewis, individually and as trustee of the assets of XLNTbrain; and John Does 1-10, individually and as trustees of the assets of XLNTbrain and alleges as follows:

1. ImPACT Applications is a Pennsylvania corporation with its principal place of business located at 9665 Granite Ridge Drive, Suite 550, San Diego, California, 92123.
2. Concussion Management, LLC f/k/a XLNTbrain, LLC is a Maryland limited liability company domiciled and operating in the state of Maryland with a mailing address of 137 National Plaza, Suite 300, National Harbor, Maryland 20745. Concussion Management, LLC trades and does business as XLNTbrain and XLNTbrain Sport.
3. Upon information and belief and based upon publicly available records, Harry Kerasidis, M.D. ("Kerasidis") is the Secretary of Concussion Management, LLC and is an adult individual and citizen of the State of Maryland with a business address of 137 National Plaza,

Suite 300, National Harbor, Maryland 20745. Kerasidis also is identified as the CEO of XLNTbrain on various web pages.

4. Upon information and belief, Steven E. Lewis ("Lewis"), at times material hereto, was the Chief Executive Officer of Concussion Management, LLC and is an adult individual and citizen of the State of Maryland with a business address of 137 National Plaza, Suite 300, National Harbor, Maryland 20745.

5. Kerasidis and Lewis are named as Defendants to this suit as both individuals and as trustees of the assets of XLNTbrain, because, according to current public filings that entity has been deemed as forfeited by the State of Maryland.

6. As such, Kerasidis and Lewis are trading and doing business as XLNTbrain and XLNTbrain Sport in their individual capacities, as partners, as sole proprietors and/or as joint venturers.

7. The John Doe Defendants are other unnamed parties that may be similarly situated to Kerasidis and Lewis and are not currently known by Plaintiff despite reasonable investigation.

8. Collectively, all entities and individuals identified as Defendants are defined and referred to herein as "XLNTbrain."

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) in that this action arises under 15 U.S.C. 1125(a).

10. This Court also has subject matter jurisdiction over the state and common law claims of false advertising and unfair competition averred herein pursuant to the provisions of 28

U.S.C. § 1338(b) in that the claims are joined with a substantial and related claim under the Lanham Act, 15 U.S.C. § 1051 et seq.

11. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and (c) because, upon information and belief, the Defendants are a limited corporation and individuals who reside in Maryland and are subject to personal jurisdiction in this judicial district at the time of commencing this action and Defendants have conducted business and committed the acts complained of in this judicial district.

FACTS ABOUT IMPACT APPLICATIONS

12. ImPACT Applications was incorporated in the Commonwealth of Pennsylvania on May 6, 2002 and was founded by a group of leading medical and research professionals.

13. ImPACT Application's primary business operations include training and software for neurocognitive testing, assessment, and evaluation for use in ImPACT Applications' proprietary computerized neurocognitive evaluation system.

14. ImPACT Applications is the maker of ImPACT® (Immediate Post-Concussion Assessment and Cognitive Testing), which provides a neurocognitive test battery that provides healthcare professionals with objective measure of neurocognitive functioning as an assessment aid and in the management of concussion in individuals ages 12-59.

15. ImPACT® was released in 2002, and represented the evolution of a computerized neurocognitive test created in 1994 and significant research that started in 1999.

16. ImPACT Applications also is the maker of ImPACT Pediatric®, which is similar to ImPACT®, but used for individuals between the ages of 5 and 11.

17. ImPACT® and ImPACT Pediatric® are the only software-based neurocognitive tests that have been cleared and designated by the Food and Drug Administration ("FDA") as Class II medical devices for use as an aid in the assessment and management of concussion.

18. Specifically, the Center for Devices and Radiological Health ("CDRH") of the FDA -- after review of a *de novo* request for classification of ImPACT® and ImPACT Pediatric® -- approved these tests as Class II medical devices on August 22, 2016.

19. ImPACT Applications expended significant amounts of time and money to obtain the aforementioned *de novo* classification of ImPACT® and ImPACT Pediatric®.

20. Specifically, ImPACT Applications submitted more than 250 peer-reviewed articles, of which half were independently conducted clinical research studies. The research publications analyzed the scientific value of the ImPACT® devices including the devices' validity, reliability and ability to detect evidence of cognitive dysfunction that might be associated with a concussive head injury. The FDA concluded that these studies provide valid scientific evidence to support the safety and effectiveness of the ImPACT® and ImPACT Pediatric® devices.

21. As a result of many years of scientific and technical rigor in developing ImPACT® and ImPACT Pediatric®, the FDA granted ImPACT Applications the imprimatur of the Class II designation -- something that XLNTbrain does not possess.

22. By clearing the *de novo* hurdle, other devices that are similar to ImPACT® and/or ImPACT Pediatric® are able to apply for similar approval from the FDA without enduring the up-front expenditures of resources and capital that ImPACT Applications made. Companies, such as XLNTbrain, are now free to submit their tests to the FDA to obtain the same designation without carrying the burden of a *de novo* submission.

FACTS ABOUT CONCUSSIONS AND THE NEED TO SCRUTINIZE CLAIMS

23. The significance of the Class II medical device classification/designation for baseline testing is of great public import considering how widespread these injuries are and the amount of public concern for these injuries.

24. Additionally, the marketing and sale of tests that appear to have the same clearance and/or qualities -- but do not -- is of equal import, but for opposite reasons.

25. For example, the ImPACT® test is used globally by approximately 7,400 high schools, 1,000 colleges and universities, 900 clinical centers, 475 consultants, 200 professional teams and military units.

26. According to the National Institute of Health, approximately 38 million children and adolescents participate in organized sports in the United States each year. Approximately 170 million adults participate in physical activities, including sports. Each year, according to the Centers for Disease Control, 1.6 to 3.8 million concussions occur in sports and recreational activities annually. (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2987636/>)(last accessed July 18, 2018).

27. According to the FDA, traumatic brain injuries account for more than 2 million emergency room visits in the United States each year, according to the U.S. Centers for Disease Control and Prevention, and contribute to the deaths of more than 50,000 Americans.

28. Considering the public health implications, companies that market concussion testing, protocols, or devices must be truthful in their claims to the public.

29. It is without question that parents with children involved in sports are particularly anxious and are vulnerable to advertisements offering potential options for the prevention, detection, and management of this condition. In fact, this subject was a focus of a Congressional

hearing on oversight of the Federal Trade Commission ("FTC") held by the U.S. Senate Commerce Committee.

FACTS ABOUT XLNTbrain AND ITS PUBLIC STATEMENTS

30. XLNTbrain, LLC was organized in Maryland on June 25, 2012. It changed its corporate name on January 6, 2016 to Concussion Management, LLC. At all times, both of these entities conducted business as XLNTbrain and/or XLNTbrain Sport.

31. The Articles of Organization for XLNTbrain, LLC states it was organized, "To assess neurological activity in athletes to enhance their performance."

32. Concussion Management, LLC was forfeited on October 13, 2017 according to the Maryland.gov web site.¹

33. XLNTbrain, according to its own web site (<http://xlntbrain.com>), markets and sells its products to schools, medical professionals, sports teams, and veterans groups, and government agencies across the country.

34. Indeed, XLNTbrain is a direct competitor of ImPACT Applications and has trailed ImPACT Applications in both research and the marketplace.

35. The XLNTbrain website states that it is "Beyond Baseline Concussion Tests." It further boasts that XLNTbrain offers, "The First Complete Online Concussion Test and Management Program for All Sports and Levels."

36. XLNTbrain also has made the following claims concerning concussion screening, return-to-play assessments, diagnosis, and care on its Internet Site, www.xlntbrain.com, and elsewhere:

¹ <https://egov.maryland.gov/BusinessExpress/EntitySearch/BusinessInformation/W14745996>

- [T]he first complete concussion management program for all sports and levels.
- [C]linical-caliber post-concussion evaluations to monitor severity and the recovery progress.
- XLNTbrain Sport provides clinical-caliber concussion care giving subscribers a complete solution that's easy to use, affordable and adds a 'virtual neurologist' for the team.
- Implementing the XLNTbrain Concussion Management Program helps safely guide athletes back to gameplay after a concussion has been sustained.
- XLNTbrain offers a complete feature set when compared to other solutions.

37. Additionally, the web site boasts that²:

Recent NFL lawsuits and exploding consumer awareness of traumatic brain injury has motivated nearly all the states in the US to establish concussion management law, mandating a certain amount of concussion management education. While these new laws have helped awareness, they have also revealed a gap in the sports teams' ability to adequately prevent, detect and protect their athletes from concussions.

XLNTbrain fills that gap, with the first complete concussion management program, assisting sports teams with a "professional-caliber" program, that delivers everything the athletes and parents, team and league officials, as well as medical professionals need to comply with state laws, and provide the highest concussion care.

38. XLNTbrain also claims that it: "helps answer the most common question, 'when can I play again?' Dr. Kerasidis created a tool that guides the decision-making process, giving all-involved individuals a recovery care plan that includes daily monitoring of symptoms, progressive physical and cognitive exertion exercises and a timeline to safely return to gameplay." Id.

² <https://www.xlntbrain.com/about/>

39. Defendants also have employed social media to push claims that XLNTbrain offers a program superior to other types of concussion assessments, including neurocognitive tests, such as the ImPACT® and ImPACT Pediatric® tests.

40. XLNTbrain asserts that it markets a “comprehensive, web-based, fully integrated sport concussion device” on its Twitter social media page.³

41. For example, in a September 5, 2019 social media post, the company posted a link to an NBC Philadelphia video titled “The Importance of Pre-Concussion Testing for Student Athletes.”⁴ In the video posted by XLNTbrain, a reporter discusses a “baseline concussion test” specifically targeted to student athletes. The reporter speaks with two practitioners at the Sadar Psychological Clinic, who extoll the importance of concussion testing.⁵

42. While the practitioners in the video do not specifically mention XLNTbrain by name, images of the XLNTbrain logo, and its slogans, such as “no one expects a concussion but head injuries happen,” are displayed prominently.⁶

43. Further, XLNTbrain’s posting of the video on its Twitter page constitutes a promotional claim for concussion use. In addition to the link, XLNTbrain’s twitter post states: “Sadar Psychological doing GREAT things to help our youth athletes battle #sportconcussions in the #Philadelphia area!”

³ XLNTBrain Sport Twitter page, *available at* <https://twitter.com/XLNTbrainSport/status/1169765337560211456> . Attached hereto as Exhibit 1.

⁴ *Id.*

⁵ NBC Philadelphia video “The Importance of Pre-Concussion Testing for Student Athletes,” *available at* https://www.nbcphiladelphia.com/news/health/Free-Concussion-Testing-Offered-to-Student-Athletes_Philadelphia-559480522.html.

⁶ *See, e.g.* NBC Philadelphia video screen capture, “The Importance of Pre-Concussion Testing for Student Athletes” at 0:38. Attached hereto as Exhibit 2.

44. It is believed and therefore averred that no premarket regulatory submission has been filed by XLNTbrain for any device or product, nor is XLNTbrain included on FDA's list of devices for assessing head injury.

45. XLNTbrain on its Internet site makes numerous public claims that the XLNTbrain test is superior to and more effective than other concussion assessment tools, including neurocognitive tests, and even make those claims by calling out ImPACT Applications by name.

46. In marketing XLNTbrain and its related products, Defendants make representations concerning its/their products, their efficacy and the market that are false and/or misleading to consumers and/or lack any scientific substantiation for the claims being made.

47. The aforementioned statements have actually mislead or have a tendency to mislead a substantial segment of Defendants' audience, and have resulted in the sale of XLNTbrain products and programs in direct competition with ImPACT® and ImPACT Pediatric®.

48. The aforementioned statements constitute general misrepresentations regarding the effectiveness and safety of XLNTbrain devices, products, and/or programs that falsely or misleadingly imply FDA review and/or approval.

49. The safety and efficacy of medical devices is within the exclusive purview of the FDA.

50. ImPACT® and ImPACT Pediatric® are the first and only medical devices recognized by the FDA to assess cognitive function following a possible concussion.

51. The Defendants' representations regarding XLNTbrain and its devices, products, and/or programs upon information and belief, do not reflect real-world conditions.

52. There is no evidence to suggest that XLNTbrain devices, products and/or programs perform at the level claimed by Defendants.

53. Defendants' statements regarding XLNTbrain and/or its devices, products, and/or programs are material to customers seeking a device to assist with concussions or the assessment of cognitive functions following a potential concussion.

54. More specifically, Defendants' statements, as described above pertain to the efficacy, safety, regulatory approval, and inherent quality of XLNTbrain and its devices, products and/or programs. Such statements are likely to influence customers' purchasing decisions, to include individual consumers, schools, sports teams, and medical professionals.

55. Defendants' advertising falsely and misleadingly implies that such results are representative of expected results under real-world conditions.

56. Defendants' advertising falsely and misleadingly implies that XLNTbrain provides benefits and results that are superior to ImPACT[®] and/or ImPACT Pediatric[®] or that any devices, products and/or programs offered by XLNTbrain possesses qualities that meet FDA criteria for an approved medical device -- a designation that XLNTbrain lacks.

FIRST CLAIM FOR RELIEF
(False Advertising in Violation of 15 U.S.C. § 1125(a) – As to All Defendants)

57. ImPACT Applications realleges and incorporates all the allegations of all prior paragraphs of this Complaint as if set forth at length herein.

58. XLNTbrain in its advertising has made express and/or impliedly false and misleading statements to consumers and the general population about its devices, products and/or programs, including without limitation statements on its website, social media, and marketing materials.

59. XLNTbrain's statements have actually mislead or have a tendency to mislead a substantial segment of XLNTbrain 's audience, and have resulted in the sale of XLNTbrain in direct competition with ImPACT Application's products, ImPACT® and/or ImPACT Pediatric®.

60. XLNTbrain's statements are material and likely to influence the purchasing decisions of customers including schools, sports teams, healthcare professionals, government agencies and other consumers that also would be consumers of ImPACT® and/or ImPACT Pediatric®.

61. The falsely advertised XLNTbrain devices, products and/or programs are sold in interstate commerce and XLNTbrain and ImPACT Applications are direct competitors for the sale of such products.

62. ImPACT Applications has been or is likely to be injured and suffer damages as a result of XLNTbrain's false statements, either by direct diversion of sales from itself to XLNTbrain or by a lessening of its goodwill.

63. XLNTbrain has and continues to obtain unjust profits as a result of its false and misleading statements.

64. XLNTbrain knows that its representations are false or misleading.

65. XLNTbrain's false and misleading representations of fact were done in bad faith and actual malice or reckless indifference to ImPACT Applications' and consumers' interests.

66. XLNTbrain's bad faith false or misleading representations of fact regarding its products abilities and qualifications makes this an exceptional case within the meaning of 15 U.S.C. § 1117.

67. XLNTbrain continues to make false or misleading representations of fact regarding its products and will continue to do so unless enjoined by this Honorable Court.

68. ImPACT Applications is entitled to an award of XLNTbrain's profits due to sales of falsely or misleadingly represented products, any damages sustained by ImPACT Applications, and the costs of the action, pursuant to 15 U.S.C. § 1117.

SECOND CLAIM FOR RELIEF
(Common Law Unfair Competition – As to All Defendants)

69. ImPACT Applications realleges and incorporates all allegations of all of the prior paragraphs of this Complaint as if set forth at length herein.

70. XLNTbrain advertises its devices, products and/or programs and conducts trade and commerce State of Maryland.

71. In doing so, it makes a representation concerning the effectiveness and safety of its devices, products and/or programs and compares its devices, products and/or programs to those of ImPACT Applications.

72. ImPACT Applications also sells its products and services in the State of Maryland.

73. Defendants knew that the statements in the XLNTbrain advertising are untrue or misleading, or by the exercise of reasonable care, should have known that the statements are untrue or misleading.

74. The false and misleading representations made by XLNTbrain in connection with the marketing of its devices, products and/or programs are and have the tendency to mislead any reasonable consumer into falsely believing that XLNTbrain is safer and more effective than they actually are -- and the XLNTbrain devices, products and/or programs are superior to ImPACT® and/or ImPACT Pediatric® in specific respects.

75. XLNTbrain's conduct constitutes false advertising and deceptive trade practices under the Maryland common law.

76. XLNTbrain has benefitted from the sale of its devices, products and/or programs to consumers who relied upon the untrue and misleading representations set forth herein.

77. XLNTbrain's false advertising has and is causing damage and irreparable harm to ImPACT Application in the form of lost profits, loss of market share, and loss of sales.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff ImPACT Applications respectfully requests that this Honorable Court enter judgment in its favor and against the Defendants on its claims as follows:

- A. granting preliminary and permanent injunctive relief prohibiting the Defendant from making false and misleading statements and requiring the Defendants to:
 - (i) immediately recall and cease all sales that are or could be derived from such a false and misleading representations; (ii) publish appropriate corrective advertising; and (iii) withdraw from any contract awarded based upon these false and misleading statements;
- B. Awarding ImPACT Applications damages in an amount to be determined to compensate ImPACT Applications for Defendants' acts of false advertising and unfair competition, together with pre-judgment and post-judgment interest thereon;
- C. Awarding ImPACT Applications the profits earned by the Defendants from the sales of XLNTbrain products, in an amount to that will be proved at trial;
- D. Finding this to be an exceptional case pursuant to 15 U.S.C. § 1117;
- E. Restitution;
- F. Awarding ImPACT Applications its cost of suit and reasonable attorneys' fees incurred in this action;

G. Awarding ImPACT Applications enhanced damages to three times the amount found or assessed by this Honorable Court for defendants willful and deliberate false advertising pursuant to 15 U.S.C. § 1117; and

H. Entering any further relief as the Court deems just in the circumstances.

DEMAND FOR JURY TRIAL

Jury trial demanded on all claims so triable.

Dated this 25th day of October 2019

Respectfully submitted,

MCNAMEE, HOSEA, JERNIGAN,
KIM, GREENAN & LYNCH, P.A.

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